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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/724,531

11/28/2000

James F. Young

10271-021-999

7010

20583

7590

04/04/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017



EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,531	Applicant(s) YOUNG ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/5/05; 11/23/05</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3-5,179-184,186,187,189,192,193,195,201,204-212,222-227,231-233,241,242,244,245,250,280-299,303 and 305-323.

Continuation of Disposition of Claims: Claims rejected are 1,3-5,179-184,186,187,189,192,193,195,201,204-212,222-227,231-233,241,242,244,245,250,280-299,303 and 305-323.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed January 13, 2006 is acknowledged and entered. Claims 1, 3-5, 179-184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 244, 245, 250, 280-299, 303 and 305-323 are pending.

Double Patenting

2. The rejection of claim 180 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of US Patent 6,656,467, is withdrawn in view of the terminal disclaimer filed October 5, 2005.

The provisional rejection of claims 3, 180 and 182 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-58 of US Patent 6,818,216, is withdrawn in view of the terminal disclaimer filed October 5, 2005.

3. (*New Rejection*) Claims 1, 3, 5, 179, 180, 182, 186, 187, 206, 212, 280-287 and 320-323 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 87, 88 and 90-118 of copending Application No. 10/020,354.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets encompass antibodies having SEQ ID NO: 48, 10, 19, 20, 39, 5 and 6.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. On December 15, 2005, a Notice of Allowability for 10/020,354 was mailed to Applicant.

4. The rejection of claim 308 is rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US Patent 5,824,307) is withdrawn in view of Applicant's amendment to claim 308. Claim 308 is now drawn to an isolated antibody comprising a complementarity determining region (CDR) having an amino acid sequence of a variable light (VL) CDR1 or VL CDR2 of the antibody P12F2. Johnson does not teach SEQ ID NO: 21 or 27 (CDR1 and CDR2, respectively).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(*New Rejection*) Claims 1, 3-5, 179-184, 186, 187, 189, 192, 193, 195, 201, 204-212, 222-227, 231-233, 241, 242, 244, 245, 250, 280-299, 303 and 305-323 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All of the claims recite, "having an amino acid sequence". It is unclear whether Applicant intends for the claims to encompass antibodies/compositions/kits comprising the entire sequence that is recited in the claim, or a portion of the sequence. For example, claim 1 could be interpreted two ways: an

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antibody comprising a variable heavy domain having a portion of amino acid sequence of SEQ ID NO: 48, or an antibody comprising a variable heavy domain having the entire amino acid sequence of SEQ ID NO: 48. The claims should be amended to clearly reflect the metes and bounds of the claims. Suggested language is, "An isolated antibody comprising a variable heavy (VH) domain having the amino acid sequence of SEQ ID NO: 48".

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen 3/28/06

Stacy B. Chen
March 28, 2006

**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

ATTY DOCKET NO.

10271-021-999

APPLICATION NO

09/724,531

APPLICANT

Young et al.

FILING DATE

November 28, 2000

GROUP

1648

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>SPC</i>	A01	09/724,396	11/28/00	Young et al.	—	—	
	A02	10/403,180	03/31/03	Young et al.	—	—	
	A03	11/230,593		Tous et al.	—	—	9/21/05
	A04	2004/0005323	01/08/04	Brams et al.	—	—	
	A05	2004/0005324	01/08/04	Pilkington et al.	—	—	
	A06	2004/0076631	04/22/04	Brams et al.	—	—	
	A07	2004/0131609	07/08/04	Young et al.	—	—	
	A08	2005/0002926	01/06/05	Young et al.	—	—	
	A09	2005/0147616	07/07/05	Young et al.	—	—	
	A10	4,800,078	01/24/89	Prince et al.	—	—	
	A11	5,667,988	09/16/1997	Barbas et al.	—	—	
	A12	5,762,905	06/09/98	Burton et al.	—	—	
	A13	6,117,980	09/12/00	Gonzalez et al.	—	—	
	A14	6,413,771	07/02/02	Brams et al.	—	—	
	A15	6,565,888	05/20/03	Tracy et al.	—	—	
	A16	6,685,942	02/03/04	Brams et al.	—	—	
	A17	6,818,216	11/16/04	Young et al.	—	—	
	A18	6,855,493	02/15/05	Young et al.	—	—	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLAS S	SUBCLA SS	TRANSLAT ION	
							YES	NO
<i>SPC</i>	B01	EP 0 699 756 A1	06/03/96	PCT	—	—		
	B02	WO 94/06448	03/31/94	PCT	—	—		
	B03	WO 96/40252	12/19/96	PCT	—	—		
	B04	WO 97/32572	09/12/97	PCT	—	—		
	B05	WO 98/33919	08/06/98	PCT	—	—		
	B06	WO 01/55217 A	08/02/01	PCT	—	—		
	B07	WO 01/64751 A	09/07/01	PCT	—	—		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

SPC	C01	Arbiza et al., "Characterization of two antigenic sites recognized by neutralizing monoclonal antibodies directed against the fusion glycoprotein of human respiratory syncytial virus," <i>J. Gen. Virol.</i> 73: 2225-2234 (1992)
	C02	Barbas et al., "Selection and evolution of high-affinity human anti-viral antibodies," <i>Trends Biotech.</i> 14(7):230-234 (1996)
	C03	Bentley and Rabbits, 1980, "Human immunoglobulin variable region genes-- DNA Sequences of Two V Kappa Genes and a Pseudogene", <i>Nature</i> 288: 730-733
	C04	Chamat et al., "Human monoclonal antibodies isolated from spontaneous Epstein-Barr Virus - transformed tumors of Hu-SPL-SCID mice and specific for fusion protein display broad neutralizing activity toward respiratory syncytial virus," <i>J. Infect. Dis.</i> 180:268-277 (1999)
	C05	Chanock et al., "Respiratory syncytial virus," <i>Viral Infections of Humans, Epidemiology and Control</i> , 3 rd Evans, ed., A.S. Chapter 20:525-544 (1989)
	C06	Chmura et al., <i>Proc. Natl. Acad. Sci. U.S.A.</i> (July 17, 2001) 98(15):8480-8484
	C07	Footo et al., "Kinetic maturation of an immune response," <i>Nature</i> , Vol. 352:530-532 (8 August 1991)
	C08	Garcia-Barreno, B. et al., "Marked Differences in the Antigenic Structure of Human Respiratory Syncytial Virus F and G Glycoproteins," <i>J. Virology</i> . 925-932 (1989).
	C09	Heard et al., "Two Neutralizing Human Anti RSV Antibodies: Cloning, Expression and Characterization," <i>Molec. Med.</i> 5:35-45 (1999)
	C10	Hefta et al., "Kinetic and affinity constants of epitope specific anti-carcinembryonic antigen (CEA) monoclonal antibodies for CEA and engineered CEA domain constructs," <i>Immunotechnology</i> 4:49-57 (1998)
	C11	Hemming et al., "Immunoglobulins in respiratory syncytial virus infections," <i>Clinical Use of Intravenous Immunoglobulins</i> , Morell and Nydegger., eds., Academic Press, London, pp. 285-294 (1986)
	C12	MedImmune, Inc., 1999, "SYNAGIS TM package insert", revised December 2, 1999
	C13	MedImmune, SYNAGIS (registered trademark) package insert, revised Oct. 23, 2002.*
	C14	Myszka et al., 1997, "Kinetic analysis of a protein antigen-antibody interaction limited by mass transport on an optical biosensor," <i>Biophysical Chem.</i> 64:127-137
	C15	Orkin and Motulsky, "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," available from http://www.nih.gov/news/panelrep.html (1995)
	C16	Palomo, C. et al., "Induction of a Neutralizing Immune Response to Human Respiratory Syncytial Virus with Anti-Idiotypic Antibodies" <i>J. Virology</i> 64(9): 4199-4206 (1990)
	C17	Roguska et al., "Humanization of murine monoclonal antibodies through variable domain resurfacing," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 91(3):969-973 (1994)
	C18	U.S. Census Bureau, Age Data, website updated May 12, 2004, http://www.census.gov/population/www/socdemo/age.html
	C19	U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, "We the American Elderly", Sep. 1993
	C20	Verma et al., "Gene therapy - promises, problems and prospects," <i>Nature</i> 389:239-242 (1997)
	C21	Wu et al., "Humanization of murine monoclonal antibody by simultaneous optimization of framework and CDR residues," <i>J. Mol. Biol.</i> 294(1): 151-62 (1999)
	C22	Wu et al., "Ultra-potent Antibodies Against Respiratory Syncytial Virus: Effects of Binding Kinetics and binding Valence on Viral Neutralization," <i>J. Mol. Biol.</i> 350: 126-144 (2005)
↓	C23	Yang et al., "CDR walking mutagenesis for the affinity maturation of a potent human anti-HIV-1 antibody into the picomolar range," <i>J. Mol. Biol.</i> 254:392-403, September 5, 1995

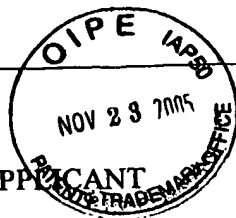
EXAMINER

Nancy B. Chee

DATE CONSIDERED

3/28/06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**LIST OF REFERENCES CITED BY APPLICANT**
(Use several sheets if necessary)

ATTY DOCKET NO.	APPLICATION NO
10271-021-999	09/724,531
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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
SBC	A19	5,929,212	07/27/99	Adair et al	—	—	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
SBC	B08	WO 99/28471	06/10/99	PCT	—	—		
↓	B09	WO 00/56771	09/28/00	PCT	—	—		
	B10	WO 00/73346	12/07/00	PCT	—	—		

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

SBC	C24	Balint and Larrick, 1993, "Antibody engineering by parsimonious mutagenesis." Gene. 137(1):109-118
	C25	Bourgeois et al., "New peptides recognizing viral epitope with tropism to mucosa - useful for, e.g. diagnosing, preventing and treating viral infection(s)." GENESEQ database entry for Accession No: AAW70933; 10/14/98 and alignment with Seq ID No: 12 of US Serial No. 09/771,415
	C26	Egan et al., 1999, "Effect of Sch 55700, a humanized monoclonal antibody to human interleukin-5, on eosinophilic responses and bronchial hyperreactivity." Arzneimittel-forschung. 49(9):779-790
	C27	Love et al., 1993, "How the anti-(metal chelate) antibody CHA255 is specific for the metal ion of its antigen: X-ray structures for two Fab/hapten complexes with different metals in the chelate." Biochemistry. 32(41):10950-10959
	C28	Sakurai et al., 1999, "Human antibody responses to mature and immature forms of viral envelope in respiratory syncytial virus infection: significance for subunit vaccines." J Virol. 73(4):2956-2962
	C29	Schier et al., 1996, "Isolation of high-affinity monomeric human anti-c-erbB-2 single chain Fv using affinity-driven selection." J Mol Biol. 255(1):28-43
↓	C30	Whitlow et al., 1995, "1.85 A structure of anti-fluorescein 4-4-20 Fab." Protein Eng. 8(8):749-761

EXAMINER	DATE CONSIDERED
Stacy B. Chen	3/28/06

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